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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,109	09/15/2003	Youcef M. Rustum	03551.0136	1832

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,109	RUSTUM ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-11,13 and 14* is/are rejected.

7)☒ Claim(s) *5 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The following is responsive to applicant's amendment received June 10, 2005.

No claims are cancelled. No new claims are added. Claims 1-14 are currently pending.

The previous objection of claim 1, set forth in paragraph 1 of the office action mailed March 9, 2005 is withdrawn in view of applicant's amendment and the remarks contained therein.

However, applicant's arguments traversing (1) the previous claim rejection under 35 USC 102(b) over Sieja (paragraph 2 of the office action mailed March 9, 2005) and (2) the previous claim rejection under 35 USC 103(a) over Sieja in view of Stockel et al., 4,617,189 and El-Bayoumy (paragraph 3 of the office action mailed March 9, 2005) have been considered but are not found to be persuasive.

Said rejections are maintained essentially for the reasons given previously in the office action mailed March 9, 2005 with the following additional comment:

Claim Rejection—35 USC 102(b) over Sieja:

Applicant argues that Sieja does not anticipate the claimed method. Specifically, Sieja discloses clinical trials involving treating patients suffering from ovarian cancer by administering to the patients a combination of cisplatin and cyclophosphamide with selenium. The claims, on the other hand, recite administration of cyclophosphamide and selenium. Therefore, Sieja cannot be deemed to inherently disclose the effect of selenium on reduction in bladder toxicity induced by cyclophosphamide.

Said arguments have been considered but are not found to be persuasive.

The examiner respectfully submits that the claims continue to be anticipated by Sieja. Sieja discloses treating patients suffering from ovarian cancer by administering a combination of selenium, cyclophosphamide and cisplatin. Applicant's claims, however, do not exclude the administration of cisplatin. The claims, as currently amended, recite "comprising" language. According to MPEP 2111.03, "[t]he transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps.");< Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). In this case, the claims do not exclude the third chemotherapeutic agent, i.e. cisplatin, taught by Sieja. Therefore, since Sieja discloses administration of the claimed "essential elements", i.e. cyclophosphamide and selenium, to an individual in need of treatment, then a reduction in bladder toxicity would be inherent

The rejection is respectfully maintained.

Claim Rejection—35 USC 103(a) over Sieja in view of Stockel and El-Bayoumy:

Applicant again submits that the prior art does not disclose the claimed method because they do not disclose using cyclophosphamide alone (i.e. without cisplatin) in combination with selenium to treat patients who suffer from ovarian cancer. The effect of selenium on the toxicity of cyclophosphamide alone is not disclosed and cannot be identified. Additionally, Stockel et al. describe the toxicity associated with cisplatin can be reduced by co administration of selenium compounds. But Stockel et al. do not teach or fairly suggest that toxicity of other agents may be affected by selenium administration. Similarly, El-Bayoumy does not address the toxicity of cyclophosphamide. Neither of the references teaches that cyclophosphamide induces bladder toxicity and that selenium reduces bladder toxicity induced by cyclophosphamide, or that higher than therapeutic doses of cyclophosphamide can be used when selenium is also administered to the individual. None of the references, either alone or in combination, renders the claimed method obvious.

Said arguments have been considered but are not found to be persuasive.

For reasons already discussed above, applicant's claims recite "comprising" language and do not exclude the administration of cisplatin as taught the Sieja reference. Furthermore, the toxicity of cyclophosphamide, although not addressed by Stockel and El-Bayoumy, is identified and discussed in the Sieja reference. Sieja solves the problem of cyclophosphamide and cisplatin toxicity by administering these agents in combination with selenium.

Stockel, discloses a method of negating the toxic effects of platinum compounds used in chemotherapy, wherein the method comprises administering to a patient in need thereof an effective amount (0.6-300 mg) of a selenium compound such as selenomethionine and methylselenocysteine. Stockel additionally discloses that the selenium compounds may be administered prior to treatment to build up levels of selenium in the body to mitigate the toxicity or the selenium compound may be administered concomitant with treatment. Please see col. 3-col. 5.

El-Bayoumy, teaches that compounds identified in selenium-enriched yeast that have been utilized in human clinical trials are selenomethionine and Se-methylselenocysteine. Please see page 133, first column, first full paragraph.

The Federal Circuit has held "all that is required for obviousness under 35 USC 103 is a reasonable expectation of success." Please see In re O'Farrell, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988). Thus, the examiner respectfully maintains it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of Sieja by administering higher than therapeutic doses of cyclophosphamide to the cancer patients because, absent evidence to the contrary, one of ordinary skill in the art would reasonably expect the selenium compound to mitigate any toxicity associated with the higher doses. Given the teachings of Sieja, Stockel and El-Bayoumy, one of ordinary skill in the art would have been motivated to increase the effective doses of cyclophosphamide and cisplatin with the reasonable expectation of aggressively treating the cancer while providing some comfort to the patient through the

mitigation of the toxic side effects associated with cyclophosphamide and cisplatin administration.

The rejection is respectfully maintained.

Conclusion

Claims 1-4, 6-11, 13, 14 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone

number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
Aug. 17, 2005

BWAYNE JONES
PRIMARY EXAMINER